HAWAII STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

STANDARD APPLICATION – CERTIFICATE OF NEED PROGRAM

Application Number 03-23

Applicant: Waimea Endoscopy, LLC
75-5995 Kuakini Hwy. #315, Kailua-Kona, HI
Phone: 808-331-0774

Project Title: Establishment of outpatient endoscopy surgicenter limited to gastrointestinal procedures
64-5188 Kinohou St., Kamuela, Hawaii

1. TYPE OR ORGANIZATION: (Please check all applicable)

Public	
Private	X
Non-profit	
For-profit	X
Individual	
Corporation	
Partnership	
Limited Liability Corporation (LLC)	X
Limited Liability Partnership (LLP)	
Other: _____	

2. PROJECT LOCATION INFORMATION:

A. Primary Service Area(s) of Project: (Please check all applicable)

Statewide:	
O`ahu-wide:	
Honolulu:	
Windward O`ahu:	
West O`ahu:	
Maui County:	
Kaua`i County:	
Hawai`i County:	X

3. DOCUMENTATION (Please attach the following to your application form):

A. Site Control documentation (e.g. lease/purchase agreement, DROA agreement, letter of intent)
SEE EXHIBIT 1 DOCUMENT OF OWNERSHIP

B. A listing of all other permits or approvals from other government bodies (federal, state, county) that will be required before this proposal can be implemented (such as building permit, land use permit, etc.) COUNTY BUILDING PERMIT, STATE LICENSURE DOH, MEDICARE CERTIFICATION

C. Your governing body: list by names, titles and address/phone numbers SOLE MEMBER/OWNER
DR. RON AH LOY CEO
SEE EXHIBIT 2 ARTICLES OF WAIMEA ENDOOSCOPY LLC

D. If you have filed a Certification of Need Application this current calendar year, you may skip the four items listed below. All others, please provide the following:

- Articles of Incorporation SEE EXHIBIT 2 WAIMEA ENDOSCOPY LLC
- By-Laws
- Partnership Agreements N/A
- Tax Key Number (project's location) TMK (3) 6-4-006-055

ADDRESS: 64-5188 KINOHOU ST.
KAMUELA,HI 96743

4. TYPE OF PROJECT. This section helps our reviewers understand what type of projec you are proposing. Please place an "x" in the appropriate box.

	Used Medical Equipment (over $400,000)	New/Upgraded Medical Equip. (over $1 million)	Other Capital Project (over $4 million)	Change in ownership	Change in service/ establish new service/facility	Change in Beds
Inpatient Facility						
Outpatient Facility					X	
Private Practice						

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5. TOTAL CAPITAL COST: $1,087,200.00

6. BED CHANGES. Please complete this chart only if your project deals with a change in your bed count and/or licensed types. Again, this chart is intended to help our reviewers understand at a glance what your project would like to accomplish. Under the heading "Type of Bed," please use only the categories listed in the certificate of need rules.

Type of Bed	Current Bed Total	Proposed Beds for your Project	Total Combined Beds if your Project is Approved
TOTAL			

7. CHANGE IN SERVICE. If you are proposing a change in service, then please briefly list what services will be added/modified. Be sure to include the establishment of a new service or the addition of a new location of an existing service. Please consult Certificate of Need Rules Section 11-186-5 for the categories of services. If you are unable to determine which category best describes your project, please consult with agency staff.

ESTABLISHMENT OF NEW OUT-PATIENT ENDOSCOPY SURGICENTER LIMITED TO GASTROINTESTINAL ENDOSCOPY AND RELATED PROCEDURES.

8. PROJECT COSTS AND SOURCES OF FUNDS (For Capital Items Only)

A. List All Project Costs:		AMOUNT:
1.	Land Acquisition	$ 355,000
2.	Construction Contract	523,000
3.	Fixed Equipment	20,000
4.	Movable Equipment	157,200
5.	Financing Costs	15,000
6.	Fair Market Value of assets acquired by lease, rent, donation, etc.	17,000
7.	Other: _____	
	TOTAL PROJECT COST:	$1,087,200.00

B. **Source and Method of Estimation**

Describe how the cost estimates in Item "A" were made, including information and methods used:

_____

_____

C. Source of Funds		AMOUNT:
1.	Cash	$ 122,000.
2.	State Appropriations	
3.	Other Grants	
4.	Fund Drive	
5.	Debt	828,000
6.	Other: LEASE/PURCHASE	137,200
	TOTAL SOURCE OF FUNDS:	$1,087,200.00

9. **IMPLEMENTATION SCHEDULE:** Please present a projected time schedule for the completion of this project from start to finish. Include all of the following items that are applicable to your project:

SEE PAGE 6

a) Date of site control for the proposed project,
b) Dates by which other government approvals/permits will be applied for and received,
c) Dates by which financing is assured for the project,
d) Date construction will commence,
e) Length of construction period,
f) Date of completion of the project, and
g) Date of commencement of operation.

Please remember that the Agency does monitor the implementation of Certificates approved. Non-implementation of a project as described in your application may result in a fine and/or withdrawal of the Certificate of Need.

10. **EXECUTIVE SUMMARY:** Please present a brief summary of your project. In addition, provide a description of how your project meets each of the Certificate of Need criteria listed below. If a new location is proposed, please attach an easy to read map that shows your project site.

a) Relationship to the Hawai`i Health Performance Plan (H2P2), also known as the State of Hawai`i Health Services and Facilities Plan
b) Need and Accessibility
c) Quality of Service/Care
d) Cost and Finances (include revenue/cost projections for the first and third year of operation)
e) Relationship to the Existing Health Care System
f) Availability of Resources

IMPLEMENTATION SCHEDULE

A. Date of site control for the proposed project of December 31, 2002.

B. Dates by which other government approvals/permits will be applied for and received.
   1. Building permit - February 2002
   2. Certificate of Need application - June through August 2003
   3. State licensure/Medicare certification - September through October 2003

C. Date by which financing is assured for the project - November 2002

D. Date construction will commence - August 1, 2003

E. Length of construction - two to three months.

F. Date of completion of the project - October or November 2003

G. Date of commencement of operation - November 15, 2003.

10. EXECUTIVE SUMMARY

Brief history. Traditionally hospitals and physicians in their private offices have provided all of the medical care since the turn of the century. In 1916 Waters opened up a downtown anesthesia clinic in Sioux City, Iowa for minor surgery in dental cases in a free-stranding center. In 1962, the University of California at Los Angeles (UCLA) instituted the first ambulatory surgical program. Soon after, in 1968, the Dudley Street Ambulatory Surgical Center opened in Providence, Rhode Island. Lacking support from insurance carriers and the State Health Department, it soon closed due to financial reasons. The Phoenix Surgery Center opened in 1970 and dedicated itself as a free-standing ambulatory facility, providing care at a lower cost than other alternatives. It has become a model for modern surgery centers.

However, the major growth in outpatient facilities did not occur until the 1980s with the enactment of the Tax Equity and Fiscal Responsibility Act (TEFRA) in 1982. Prospective payment for inpatient care with diagnosis related groups (DRG), Medicare reimbursement was now higher for the same procedures performed in an outpatient setting since they were not included in DRGs. Third party carriers soon followed with similar reimbursement differences. Improvements in technology further allowed many surgical, diagnostic and therapeutic procedures to be performed safely in an outpatient setting. Hospitals and proprietary groups that include physicians have discovered the advantages of outpatient care. This discovery led to an expansion of outpatient centers in the 1980s. See Exhibit 3, The Growth of Ambulatory Surgery.

Ron Ah Loy, MD has been practicing gastroenterology on the north and west side of The Island of Hawaii since 1992. There has been considerable population growth over the past decade in the County of Hawaii.

Available data from Hawaii Department of Business, Resident Population was 121,458 in 1990; ten years later it was 148,677, an increase of almost 25%! See Exhibit 4, 5 and 6. However, the subset of the population most likely to utilize GI endoscopy procedures, ages 45 and over, almost doubled over this same period, from 32,000 to 58,000, thereby increasing the need for these services on The Big Island.

Waimea Endoscopy, LLC, a newly formed organization, owned by Ron Ah Loy, MD seeks to establish an independent endoscopy ambulatory surgery center.

Description. The property is located at 64-5188 Kinohou Street in Waimea or Kamuela, Hawaii, approximately one-fourth mile east of the North Hawaii Community Hospital. See Map of Area - Exhibit 7. The project will consist of a new GI endoscopy facility and an adjoining medical clinic with a total gross area of 5,480 square feet. The operation of the endoscopy portion of the facility will utilize licensed physicians and medical professionals. The facility will be comprised of a single endoscopy procedure room, separate adjoining scope cleaning room, a preoperative and postoperative recovery area, a lavatory, nurse's station, reception/business office, patient/family waiting area, storage for endoscopy equipment and supplies, patient locker room, staff locker room, staff

lavatory and shower, oxygen supply and external generator (see drawing of first floor of facility - Exhibit 8).

A. Relation to H2P2. Waimea Endoscopy, LLC, proposed facility's goals are to increase span of healthy life for Hawaii residents, eliminate preventable illness, disability and premature death, reduce healthcare disparities among Hawaii residents and achieve equitable and effective access for services provided at reasonable cost to all Hawaii's people. Many of the State's objectives are consistent with the objectives of the proposed facility such as,

   I. Early detection and diagnosing of treatable diseases such as esophageal, gastric and colon cancer.

   II. Reducing the effects of chronic disease such as gastroesophageal reflux disease and peptic ulcer disease by properly diagnosing and treating appropriately to minimize short and long-term complications.

   III. Reducing morbidity and pain through timely and appropriate diagnostic and therapeutic intervention such as screening colonoscopies to prevent colon cancer.

   IV. Establishing a regional delivery system that includes community input, is cost effective and foster improved access to quality healthcare services such as proposed by the specialty GI endoscopy center on the northwest side of The Island of Hawaii.

B. Need and Accessibility. Establishment of the proposed facility would substantially benefit the community in terms of reduced healthcare costs and favorably impact quality of care. The proposed ambulatory surgicenter should reduce overall healthcare costs directly by reducing the cost of endoscopic procedures for both patient and insurer without the use of public funds.

   Regional and national data indicate higher rates of utilization and increasing trends for GI procedures performed in the outpatient setting (see Table of Utilization Rates (Exhibit 11). US nationwide data revealed there were 4.0 to 4.8 million GI endoscopic procedures performed per year by estimates obtained from CDC and NIH in the fiscal year 2000. (Source is via telephone interview with Dr. J Everhart, Epidemiologist, NIH, Bethesda, Maryland.) This translates to approximately 18 procedures per 1000 persons per year. Estimate statewide, obtained in the same year 2000, were approximately 38,000 GI procedures performed per year for utilization rate of 32 procedures per 1000 persons per year. However, for the population serviced by the proposed facility, the utilization rate was only 12 procedures per 1000 persons per year for the year 2000. Whereas in Hilo, where a GI endoscopy ambulatory surgery center exists, its utilization rate was more in keeping with the rest of the State at approximately 35 procedures per 1000 persons per year (see Exhibit 11).

   These figures indicate a significant disparity for these services on The Big Island and a need already exists and will continue to increase as the population also increases.

Based upon these estimates and utilization rates, Waimea Endoscopy, LLC, submits an estimate of 25 to 35 procedures per 1000 persons per year over years one through three of operation, resulting in approximately 1600 to 2400 procedures performed per year. Currently the GI endoscopy ASC in Hilo, serving the east Hawaii residents, perform approximately 3600 procedures per year.

The target group of patients ages 45 and older, who are most likely to utilize GI endoscopic procedures, have increased from 32,000 to 58,000 in the County of Hawaii from 1990 to fiscal year 2000. This translates to a growth of approximately 75% increase over a ten year period or averaging 7.5% per year. Approximately 46% of this increased population growth occurred in the service area of the proposed ASC.

Colorectal cancer ranks third in incidence among men and women and is the second leading cause of death in the United States, accounting for 56,000 deaths annually. There are 130,000 newly diagnosed cases of colorectal cancer per year. Because adenomatous polyps are believed to be the precursor lesions to colorectal cancer, effective screening tools must accurately detect these premalignant lesions. Although several screening modalities such as annual fecal occult blood test, flexible sigmoidoscopy every five years and double contrast barium enema every five to ten years have been recommended, colonoscopy has emerged as the "gold standard" because of its superiority over other modalities for detecting polyps and cancer (see Exhibit 12, Geoffy TL Screening for Colorectal Cancer: The Role of Colonoscopy, The Resident Reporter, Journal of the American Gastroenterologic Association, Issue November 2001, pages 50-53).

These data support the utility of colonoscopy, which is the GI procedure provided at the proposed facility, which will fulfill a need and increase accessibility to this well recognized tool for early cancer detection.

Cancer incidence varies amongst all the ethnic groups in Hawaii with the preponderance among the Japanese and Native Hawaiian population. The Japanese people rank number one for stomach and colorectal cancer for both men and women. Native Hawaiians rank number two for stomach cancer among men and women and number two for rectal cancer in women, and number three for rectal cancer in men. In addition, Native Hawaiians have the highest overall cancer mortality among the five major ethnic groups in Hawaii (see Exhibit 13, Update on Cancer Incidence in Native Hawaiians for 1995 to 2000 from Cancer Research Center of Hawaii).

Therefore, ethnic groups who show an increased need for GI procedures include the Japanese and Native Hawaiian population because of their increased incidence of both gastric and colon cancer. Given the fact that the utilization rates are significantly lower on the north and west sides of The Island the proposed GI endoscopy facility would fulfill a need and eliminate the disparity for these needed services among the general population at large and, in particular, those ethnic groups who appear to have a higher incidence of GI malignancies in Hawaii.

This demand will continue to increase proportionally if Hawaii County's population continues its growth pattern of approximately 2% to 3% per year. This, of course, will be reflected in the proportionate increase in the target population ages 45 and older.

C. Quality of Service/Care. The proposed facility will be required to be a licensed provider and, therefore, will require licensure from the State Department of Health, be federally certified by Medicare and will also be a Medicaid provider. The Waimea Endoscopy, LLC will also utilize quality assurance policies (see Exhibits 9 and 10, Mission Statement and Quality Assurance Program). It will provide for ongoing staff training specializing in GI endoscopy. The owner/applicant is Board Certified in Gastroenterology.

All of these elements will set and maintain the standards of medical care aimed at providing good quality GI specialty care in the community.

D. Cost and Finances. The proposed free-standing GI ambulatory surgery center would reduce costs. Currently GI endoscopy procedures are performed in the hospital setting and cost 40% to 50% higher than in an ASC. These higher costs are, in part, the result of a higher overhead cost inherent in operating a functioning well equipped and staffed Operating Room 24 hours a day, which is required to provide a wide array of surgical procedures. In addition, other ancillary services provided by the hospital may contribute to the increased cost of doing business. Whereas ASCs are not open 24 hours and are equipped to provide services limited to gastroenterology procedures.

In addition, HMSA, the largest private insurer in the State of Hawaii indicated recently (February 1, 2003) that charges for anesthesiology services utilized for GI procedures will no longer be covered. Kona Community Hospital utilizes anesthesiologists exclusively for all GI procedures except sigmoidoscopies. This places a significant out-of-pocket burden and barrier for this subset group of patients.

Comparative costs between facility charges and ASC are quite variable. Conservative estimates derived from patient's claims have averaged between $900 to $1200 per GI procedure performed in a hospital setting but may run as high as $2000 per procedure; whereas, facility charges that are determined by insurers, average approximately $400 per procedure.

HMSA and Medicare recognize this opportunity for cost reduction and have provided incentives and favorable regulations to encourage patients and physicians to utilize outpatient procedures in non-hospital settings when appropriate. This, in turn, should translate to reduce overall healthcare costs for the entire community. This would be another reason for the increased demand and need for these services to be performed in an outpatient setting.

Furthermore, allowable charges for procedures performed at a ASC are largely predetermined by insurers and average in the range of $400 to $500 per procedure, significantly less than the $900 to $1200 per procedure charges in the hospital setting (these hospital charges are conservative estimates. Actual

charges obtained by the applicant from patient's hospital statements are often in excess of $2000 per procedure, not including an additional $150 to $750 for the anesthesiology service).

Waimea Endoscopy, LLC will work to eliminate any barriers, physical or otherwise to the accessibility to services provided by the proposed facility.

Cost and Finances. Section B and the exhibits on page D2a and D2b support the immediate and long term feasibility of the proposed endoscopy ASC. Waimea Endoscopy, LLC estimates a project capital cost of $1,087,200.00 including land acquisition, construction costs, equipment purchase and financing costs. This is to be financed with personal funds, conventional loans and equipment leasing. Based upon the estimated revenue and expenses set forth in this application, revenue should be sufficient to service debt (See exhibit D2a and D2b, Revenues and Expenses).

E. Relationship to the Existing Healthcare System. The proposed endoscopy ASC will benefit the existing healthcare system by adding a new facility, which will improve current outpatient services, health needs and future demands for these services as indicated by the lower utilization rates and population growth data and will do so at a reduced cost. The proposed ASC will also fill an existing gap in the healthcare delivery pattern by providing a facility that meets many of the unmet needs and demands of the community.

The demands for outpatient endoscopy services has risen because of a number of factors. These include advance technology to perform these procedures safely and effectively in an outpatient setting, such as the use of monitoring equipment and medical personnel trained to provide perioperative care in these settings. In addition, when compared to utilization rates with East Hawaii, state and national data there appears to be a significant disparity with lower utilization rates existing in the north and west side of The Island. Compounding these lower rates is the fact that over the past year Kona Community Hospital has set a limit for endoscopy procedures performed by the applicant on his block day from 15 to 10 procedures, a reduction of 30%. This has also contributed to the lower rate of utilization and supports the need for services that can be rendered by the proposed endoscopy ambulatory surgery center. In addition, Medicare has recommended colon screening for individuals 50 and over, endorsing colonoscopy as a vital screening tool. It is anticipated other insurers will adopt similar guidelines. See exhibit 20, Medicare B News, Issue 189, pages 12-13, April 25, 2001. Understandably, other factors, such as the increasing population and, in particular, the target group ages 45 and older, and certain ethnic groups, such as Japanese and Native Hawaiian, who have an increased risk for GI malignancies and warrant increased surveillance, will also benefit by the increased access to specialty care. No less important will be the ability of the proposed facility to free up the existing facilities Operating Rooms for patients needing acute surgical care (see support letters of local surgeons and CEO - Exhibit 16 A, B and C).

Waimea Endoscopy, LLC will meet with both acute care hospitals in the area to improve the community's healthcare system. In addition, Waimea Endoscopy,

LLC believes that the size and nature of the proposed facility will have minimal impact on the existing healthcare system.

H2P2 guiding principles allowing the establishment of a free standing ambulatory center (less than 24-hour stay) such as the proposed ASC, item 11.c, page II-9, states, "For a new or additional ambulatory surgery operating room, all other comparable operating rooms in the service area average a minimum of 1600 hours per room utilization per year. A telephone survey of the hospitals on the Big Island indicates operating room utilization of 80% or less. (Kona Community Hospital 80%, North Hawaii Community Hospital 50% to 60%, Hilo Medical Center 63%). However, hospital operating rooms are not comparable for the following reasons; 1) The operating room needs to be available 24 hours, 365 days a year; 2) Provide services for a variety of surgical procedures, i.e., general surgery, OB-Gyn, orthopedics, ENT, etc, 3) Provide for emergency surgical procedures; 4) Provide 24-hour on-call nursing, anesthesiology and surgical staff coverage. The result is higher health care costs for procedures that could be performed in an endoscopy ASC.

The proposed Endoscopy ASC will provide single specialty non-emergent endoscopic procedures seven to eight hours per day, five to six days per week at less cost. For appropriate threshold comparison, the only comparable operating room in the service area is the Endoscopy Center, run by Gastroenterology Associates in Hilo. Currently, as of July 2003 data provided by their office manager, the operating room utilization is averaging 53 hours per week, or 8.8 hours per day. Based on 8.8 hours per day for 250 days per year, the Endoscopy Center's utilization is 2200 hours per room per year, exceeding the capacity threshold of 1600 hours per room by 600!

In addition, residents residing in the North and West sides of the Island need to travel one to two hours (50 to 100 miles) one way in order to have a GI endoscopy procedure performed in a comparable facility as that proposed by the applicant.

These data support the need for the establishment of a new ambulatory endoscopy surgery center as proposed by Waimea Endoscopy, LLC.

The proposed ASC will also supply the community with an additional surgical facility in the event of a disaster or emergency.

F. Availability of Resources. Waimea Endoscopy, LLC has access to the capital to complete the project and successfully implement and operate the proposed endoscopy ASC. The project will be privately financed and will not seek public or government funding sources (see exhibit D-4 and page 4, Source of Funds)

Sources of funding include personal funds of $122,000, commercial loan (First Hawaiian Bank) of $828,000, equipment lease/purchases Olympus Corporation (endoscopy equipment) $100,000, Physician Sales and Service, Inc (PSS) (monitoring equipment, crash cart, defibrillator) $37,200.

Staffing requirements include two RNs, one receptionist, one surgical scope tech, and one billing clerk (for staff description see Exhibit 17 - Description of ASC Staff). Waimea Endoscopy, LLC is confident in acquiring qualified personnel based upon informal inquiries and interviews with qualified persons residing in the community.